

Mar 10, 2025

ANGELA E. NOBLE
CLERK U.S. DIST. CT.
S. D. OF FLA. - FTLUNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 0:24-cr-60213-DSL

UNITED STATES OF AMERICA

vs.

RICARDO ACUNA,

Defendant.

CT. EXH. 2

FACTUAL PROFFER IN SUPPORT OF GUILTY PLEA

If this matter were to proceed to trial, the parties agree that the United States, by and through the United States Attorney for the Southern District of Florida and the Consumer Protection Branch of the United States Department of Justice (the "Government"), would be able to prove the following facts beyond a reasonable doubt. The defendant, Ricardo Acuna, understands and agrees that these are not all the facts that the Government would prove if the case proceeded to trial but are sufficient to prove the charge of conspiracy as alleged in the Information filed in this case.

Beginning at least in or around January 2019 and continuing through at least in or around January 2020, within the Southern District of Florida and elsewhere, the defendant, Ricardo Acuna, did willfully, that is, with the specific intent to further the objects of the conspiracy, and knowingly combine, conspire, confederate, and agree with persons known and unknown to the United States Attorney to commit an offense against the United States, in violation of Title 18, United States Code, Section 371, by knowingly and with intent to defraud devising, and intending to devise, a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that they were false and fraudulent when made, and transmitting and causing to be transmitted, by means of wire

communications in interstate commerce, writings, signs, signals, pictures, and sounds, for the purpose of executing the scheme, in violation of Title 18, United States Code, Section 1343.

During the conspiracy, the defendant was a co-owner of A&R Research Group LLC ("A&R"), a medical research clinic located in Pembroke Pines, Florida that conducted clinical research trials of new drugs on behalf of drug trial sponsors ("sponsors"). The defendant co-owned A&R with his wife, Angela Baquero ("Baquero"), who served as A&R's clinical research director or manager and as the study coordinator for clinical trials undertaken by A&R. The defendant served as A&R's regulatory and contract affairs manager throughout the conspiracy. In this role, the defendant maintained all the regulatory binders with the study documents, collected signatures from the clinical investigator, sub-investigators, and Baquero on the regulatory paperwork, completed the forms and documents required at the beginning of the studies, collected any required documents to send to regulators, and completed any questionnaires required by the institutional review board. The defendant was also the primary contact for the sponsors. In order to conduct clinical trials, A&R worked with Clinical Investigator, who was a licensed physician in Florida. A&R used the same clinical investigator for all of its clinical trials.

Between at least in or around January 2019 and at least in or around January 2020, A&R conducted two clinical research trials on behalf of a sponsor. The two clinical research trials concerned investigational drugs intended to treat patients suffering from moderate to severe asthma and mild to moderate asthma (collectively, "the asthma trials"). In the context of a clinical research trial, a participant or patient is referred to as a study or trial "subject." A&R was paid a total of \$320,247.98 by the sponsor to conduct the asthma trials.

Prior to beginning the clinical trials, the defendant (on behalf of A&R) and Clinical Investigator entered into a Clinical Trial Agreement for each of the asthma trials with the Contract

Research Organization (“CRO”), which was acting on behalf of the drug sponsor. By signing the Clinical Trial Agreements, the defendant knew that A&R and Clinical Investigator were required, among other things, to follow the trial protocol and applicable federal regulations. The defendant also had direct knowledge of the trial protocols for the asthma trials as he signed the Site Delegation of Authority Logs for each trial in February and March 2019, respectively. By signing the delegation logs, the defendant acknowledged that he was delegated—and able to perform—certain tasks as part of the studies. The defendant also received training from the CRO prior to beginning the asthma trials at A&R.

The defendant knew that A&R had been retained to perform the asthma trials honestly and accurately, and in accordance with the clinical trial protocol and applicable federal regulations. The defendant also knew that the sponsor, CRO, and FDA could conduct an audit of the A&R trial site at will, and that A&R and its staff were required to cooperate with the auditors and allow access to all trial documentation and facilities.

The purpose of the conspiracy was for the defendant and his co-conspirators to unlawfully enrich themselves by: (1) making materially false and fraudulent representations regarding, among other things, subject eligibility for and participation in the asthma trials to cause the sponsor and/or CRO to make payments on the contracts for the asthma trials, and (2) falsifying and fabricating material documents and data in the asthma trials, including case histories, spirometry readings, echocardiogram data, and other data.

The defendant and his co-conspirators knew that A&R and the subjects enrolled in the asthma trials did not participate in the clinical trials in accordance with the trial protocols and applicable federal regulations. For purposes of obtaining money by means of materially false and fraudulent pretenses, representations, and promises, the defendant and his co-conspirators,

including Co-Conspirator 1 and Co-Conspirator 2, obtained fake medical records for at least seventeen trial subjects so that the subjects could enroll in the asthma trials despite having no legitimate documentation of a qualifying asthma diagnosis. Once Co-Conspirator 1 and Co-Conspirator 2 delivered the fake medical records to A&R, the defendant issued payments to Co-Conspirator 1 and Co-Conspirator 2 for obtaining the false records. For example, on or about June 12, 2019, the defendant signed and issued a check on behalf of A&R for \$120 to Co-Conspirator 1 for fake medical records on behalf of two trial subjects.

In furtherance of the conspiracy, Baquero would direct Co-Conspirator 1 and Co-Conspirator 2 to perform spirometry readings and provide blood samples for other subjects enrolled in the asthma trials, and the defendant would later issue payments to Co-Conspirator 1 and Co-Conspirator 2 for these additional fraudulent study assessments. For example, on or about May 28, 2019, the defendant signed and issued a check on behalf of A&R for \$150 to Co-Conspirator 2 for "4 Spirometries," which the defendant knew was to pay for Co-Conspirator 2 having performed the spirometry tests on behalf of other subjects purportedly enrolled in the asthma studies. The defendant did not include this check to Co-Conspirator 2 for "4 Spirometries" in any of the records related to the asthma trials. These spirometry readings and blood samples were then submitted to the CRO and sponsor for the purpose of duping them into believing that the trial subjects were participating in the trial and that A&R was conducting the asthma studies in accordance with the clinical trial protocol.

In or around August 2019, based, in part, on the suspicious nature of the spirometry and echocardiogram readings submitted by A&R, the sponsor performed an in-person audit of A&R. During that audit, the defendant and Baquero provided the sponsor with the case histories, which the defendant knew contained records of payments to subjects who did not participate in the asthma

studies. On or about January 24, 2020, these case histories, which the defendant knew contained records of payments to subjects who did not participate in the asthma studies, were provided to an FDA investigator during the course of an FDA inspection.

In total, the defendant's conduct described herein, including his false and fraudulent representations regarding the asthma trials, resulted in payments in the amount of \$320,247.98 from the sponsor to A&R, which was jointly controlled and owned by the defendant and Baquero.

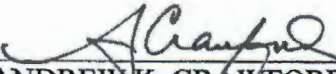
The foregoing facts do not describe all of the details of the scheme, or the defendant's complete knowledge of the scheme, but are offered for the limited purpose of establishing a sufficient basis to support the defendant's plea of guilty to the charge of conspiracy.

HAYDEN P. O'BYRNE
UNITED STATES ATTORNEY

AMANDA LISKAMM
DIRECTOR
U.S. DEPARTMENT OF JUSTICE
CONSUMER PROTECTION BRANCH

Date: March 5, 2025

By:


ANDREW K. CRAWFORD
TRIAL ATTORNEY
U.S. DEPARTMENT OF JUSTICE
CONSUMER PROTECTION BRANCH

Date: March 5, 2025

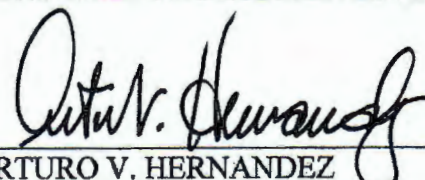
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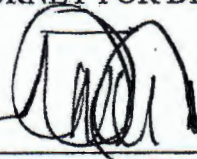
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Date:

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By:


RICARDO ACUNA
DEFENDANT